

REMARKS

The Examiner's Office Action mailed March 5, 2009, which rejected all pending claims, has been reviewed. Reconsideration of claims 1-8 in view of the following amendments and remarks is respectfully requested. Moreover, Applicants have reviewed the Office Action of March 5, 2009, and submit that the following Remarks are responsive to all points raised therein. Applicants believe that currently pending claims 1-10 are now in form for allowance.

Status of Claims

Claims 1-10 are pending in the application. Claims 1-4 have been amended. New claims 5-10 have been added. Support for the amendment to claim 1 can be found, for example, at page 2, line 21 to page 4, line 7; page 6, line 20; and page 7, lines 1-5, of the specification. Claims 2-4 have been amended for clarity. Support for new claim 5 can be found, for example, at page 2, line 21 to page 3, line 19 of the specification. Support for new claim 6 can be found, for example, at page 2, line 21 to page 3, line 19 of the specification. Support for new claim 7 can be found, for example, at page 4, lines 2-9 of the specification. Support for new claim 8 can be found, for example, at page 4, line 10, to page 5, line 7 of the specification. Support for new claim 9 can be found, for example, at page 7, line 3 of the specification. Support for new claim 10 can be found, for example, at page 7, line 5 of the specification. No new matter has been added.

Rejection of Claim 1 and 4 under 35 USC §102(b)

Reconsideration is respectfully requested of the rejection of claims 1 and 4 under 35 U.S.C. §102(b) as being anticipated by Ursua et al. (EP 1,177,788).

Applicants have amended claim 1. Ursua et al. does not teach all of the elements of amended claim 1 and as such, Applicants respectfully request withdrawal of the present rejection. Claim 4, directly or indirectly, depends from claim 1, and as such Applicants request withdrawal of the present rejection with respect to claim 4.

Rejection of Claim 1 and 4 under 35 USC §102(b)

Reconsideration is respectfully requested of the rejection of claims 1 and 4 under 35 U.S.C. §102(b) as being anticipated by Murphy et al. (US 5,256,699).

Applicants have amended claim 1. Murphy et al. does not teach all of the elements of amended claim 1 and as such, Applicants respectfully request withdrawal of the present rejection. Claim 4, directly or indirectly, depends from claim 1, and as such Applicants request withdrawal of the present rejection with respect to claim 4.

Rejection of Claim 1 and 4 under 35 USC §102(b)

Reconsideration is respectfully requested of the rejection of claims 1 and 4 under 35 U.S.C. §102(b) as being anticipated by Wadhwa et al. (US 2003/0170310).

Applicants have amended claim 1. Wadhwa et al. does not teach all of the elements of amended claim 1 and as such, Applicants respectfully request withdrawal of the present rejection. Claim 4, directly or indirectly, depends from claim 1, and as such Applicants request withdrawal of the present rejection with respect to claim 4.

Rejection of Claim 1 under 35 USC §102(b)

Reconsideration is respectfully requested of the rejection of claim 1 under 35 U.S.C. §102(b) as being anticipated by Lech et al. (US 5,681,577).

Applicants have amended claim 1. Lech et al. does not teach all of the elements of amended claim 1 and as such, Applicants respectfully request withdrawal of the present rejection.

Rejection of Claims 1, 2, and 4 under 35 USC § 103(a)

Reconsideration is requested of the rejection of claims 1 and 3 under §103(a) as being unpatentable over Fekete et al. (WO 01/12162) in view of Vetter et al. (US 5,808,076).

"Section 103 forbids issuance of a patent when 'the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.'" *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1734, 82 USPQ2d 1385, 1391 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including (1) the scope and content of the prior art, (2) any differences between the claimed subject matter and the prior art, (3) the level of skill in the art, and (4) where in evidence, so-called secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 148 USPQ 459, 467 (1966). See also *KSR*, 127 S.Ct. at 1734, 82 USPQ2d at 1391 ("While the sequence of these questions might be recorded in any particular case, the [Graham] factors continue to define the inquiry that controls.")

The present invention is directed to a solid pharmaceutical formulation that includes a quinolone antibiotic, 4 to 20 % by weight of a flavoring which is a mixture of proteins, fats, and carbohydrates, and, at least 1.5% to 15% by weight of colloidal silicon dioxide based on the total weight of the finished formulation. The ratio by weight of colloidal silicon dioxide to flavoring is 1:4 to 1:1.

The problem of the present invention was to provide solid pharmaceutical compositions which are well accepted by animals and have good mechanical properties. The composition of the present invention contains comparatively high amounts of flavors which are mixtures of proteins, fats and carbohydrates. These flavors make the composition more attractive to animals (e.g. dogs). Such flavors have a negative influence on the mechanical properties of the solid compositions (e.g. tablets). Applicants have found that by adding suitable amounts of silicon dioxide the mechanical (and other) properties of the tablets can be improved. In addition, Applicants have found that in the compositions according to the present invention the flavor retains its functionality in spite of the use of a considerable amount of colloidal silicon dioxide which according to the prior art is taste-masking (See results of acceptance tests in section IV. on page 16 of the specification).

Fekete et al. disclose an immediate release Ciprofloxacin tablet. Although, the Examiner is correct that Fekete et al. disclose maltodextrin, Applicants disagree that maltodextrin is a flavoring as required in claim 1. Claim 1 requires a flavoring that is a mixture of proteins, fats, and carbohydrates. Maltodextrin is a short chained starch sugar, i.e. a carbohydrate. Fekete et al. do not disclose a mixture of proteins, fats, and carbohydrates at all. In fact, Fekete et al. do not even disclose a flavor, as maltodextrin is used as a binder. Finally, and more importantly, Fekete et al. would be seen to teach away from the present invention, i.e. flavored tablets. Fekete et al. teach the use of silicon dioxide and at the time of the invention it was known that silicon dioxide is a taste-masking agent. Someone skilled in the art knowing that silicon dioxide is a taste-masking agent would not add flavor to a silicon dioxide formulation and expect to get a flavored formulation, which is one of the goals of the present invention.

Vetter et al. disclose certain embonate preparations of quinolone antibiotics. The document suggests various formulations including suspensions, gels and tablets. Although, the Examiner is correct that Vetter et al. do teach a tablet with enrofloxacin and colloidal silica, Applicants submit that Vetter et al. teach away from the present invention. As noted above for Fekete et al., it was known that silicon dioxide is a taste-masking agent. As such, someone skilled in the art would not add flavor to a formulation that included silicon dioxide (such as Vetter et al.'s) and expect to get a flavored formulation as in the present invention. Finally, the amount of silicon dioxide present in the examples of Vetter is a lot lower (0.15%) than the amount required according to the present invention.

As both Fekete et al. and Vetter et al. teach away from the present invention and would not motivate someone skilled in the art to the solid pharmaceutical formulation of the present invention, Applicants request that the present rejection to claim 1 be withdrawn. Claims 2 and 4, directly or indirectly,

depend from claim 1, and as such Applicants request withdrawal of the present rejection with respect to claims 2 and 4.

Rejection of Claims 1-4 under 35 USC § 103(a)

Reconsideration is requested of the rejection of claims 1-4 under §103(a) as being unpatentable over Fekete et al. (WO 01/12162) in view of Vetter et al. (US 5,808,076) and Daube et al. (DE 10224086).

Applicants submit that Daube et al. is not prior art to this patent application Daube was not published prior to the invention by the Applicants and Daube published less than one year prior to the date this application was filed in the United States (Applicant's PCT date). Since the rejection with regards to the other two references was addressed above, Applicants request that the present rejection of claims 1-4 be withdrawn.

Conclusion

Applicants respectfully submit that the pending claims are now patentable and in form for allowance.

The Commissioner is hereby authorized to charge any fee deficiency or credit any overpayment in connection with this amendment to Deposit Account No. 50-4260.

Respectfully submitted,
/JESSICA MONACHELLO/
Jessica Monachello
Reg. No. 58,015
BAYER HEALTHCARE LLC
P.O. Box 390
Shawnee Mission, KS 66201
Tel: 913-268-2038
Fax: 913-268-2889